

Addendum to the Quality Assurance Standards for DNA Databasing Laboratories performing Rapid DNA Analysis and Modified Rapid DNA Analysis Using a Rapid DNA Instrument

This addendum to the Quality Assurance Standards describes the quality assurance requirements that accredited laboratories performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument on reference samples (i.e., offender, arrestee, detainee or casework reference sample) for inclusion in the Combined DNA Index System (CODIS) or are performing Rapid DNA analysis or modified Rapid DNA analysis on casework reference samples for forensic casework comparison shall follow to ensure the quality and integrity of the data. These Standards also apply to vendor laboratories that perform Rapid DNA analysis or modified Rapid DNA analysis testing on reference samples (i.e. offender, arrestee, detainee or casework reference sample) in accordance with Standard 17. This addendum to the Standards does not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

Laboratories performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument for the analysis of reference samples shall follow these Standards in conjunction with the publicly available minimum standards issued by the FBI Director (*Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories* effective September 1, 2011). For laboratories performing modified Rapid DNA analysis using a Rapid DNA instrument, the interpretation and technical review shall be conducted manually.

EFFECTIVE DATE:

These standards shall take effect December 1, 2014.

1. SCOPE

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

2. DEFINITIONS

Except as noted below, the Standard shall be followed and applied as documented in the Quality Assurance Standards (QAS) for DNA Databasing Laboratories effective September 1, 2011.

Additional definitions include:

Cartridge lot number is an identification number assigned to a particular quantity or lot of material having uniform character and quality within specified limits from a single manufacturer.

Modified Rapid DNA analysis describes the automated (hands-free) process of developing a CODIS Core STR profile from a known reference sample. This “swab in – profile out” process consists of automated extraction, amplification, separation, and detection without human intervention but requires manual interpretation and technical review.

Negative sample control is used to detect DNA contamination in all of the Rapid DNA reagents and consumables.

Positive sample control is an analytical control sample that is used to determine if the Rapid DNA instrument is performing all steps of the process properly. This control consists of a known DNA sample (biological material whose DNA type is known or established) that shows concordant results at all loci with a validated laboratory process.

Rapid DNA analysis describes the fully automated (hands-free) process of developing a CODIS Core STR profile from a known reference sample. The “swab in – profile out” process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

Rapid DNA cartridge is a preassembled set of reagents for performing extraction, amplification and/or separation on a Rapid DNA instrument.

Rapid DNA instrument describes the automated device that carries out the Rapid DNA analysis or modified Rapid DNA analysis.

Reference samples are offender, arrestee, detainee or casework reference samples.

3. QUALITY ASSURANCE PROGRAM

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

4. ORGANIZATION AND MANAGEMENT

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

5. PERSONNEL

Except as noted below, Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

5.1.2.2.4 Analysts and technicians shall have documented training for operating the Rapid DNA instrument.

5.1.2.2.5 Analysts and technicians shall have documentation of successfully completing a competency test prior to independently operating the Rapid DNA instrument.

6. FACILITIES

Except as noted below, Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Standard 6.1.4 shall not be applicable to a Rapid DNA instrument.

6.1.6 A Rapid DNA instrument may be used for processing reference samples provided that it has been validated in accordance with Standard 8.

6.1.6.1 If a Rapid DNA instrument is used to carry out DNA processing for reference samples, analysis shall be performed in a pre-amplification room.

7. SAMPLE CONTROL

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

8. VALIDATION

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

9. ANALYTICAL PROCEDURES

Except as noted below, Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

9.3 The laboratory shall identify critical reagents and evaluate them prior to use in the laboratory. These critical reagents shall include, but are not limited to, the following:

9.3.3 Rapid DNA cartridge(s)

Standards 9.5.1, 9.5.2 and 9.5.3 shall not be required for a Rapid DNA instrument.

9.5.5.1 The laboratory shall check its Rapid DNA analysis and/or modified Rapid DNA analysis procedures annually or whenever upgrades and/or changes are made to the instrument against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

9.5.6 For Rapid DNA analysis or modified Rapid DNA analysis, a laboratory shall have and follow documented procedures to address the use of positive sample controls and negative sample controls for Rapid DNA instruments.

9.5.6.1 The laboratory shall monitor the Rapid DNA analysis process using the following standards:

9.5.6.1.1 Each sample shall contain an Internal Lane Standard (ILS).

9.5.6.1.2 An allelic ladder shall be included with each instrument run.

9.6.2 For modified Rapid DNA analysis, the laboratory shall:

9.6.2.1 Verify the Internal Lane Standard (ILS) and allelic ladder results meet the laboratory's interpretation guidelines for all data to be entered into CODIS.

- 9.6.2.2 Perform manual interpretation of the data generated.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

Except as noted below, Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Standards 10.2.1 through 10.2.1.8 and 10.4.1.1 through 10.4.1.5 shall not be applicable to a Rapid DNA instrument.

- 10.2.2 The following critical equipment requires quarterly recertification and/or performance checks:

- 10.2.2.2 Rapid DNA instrument

- 10.4.1 At a minimum, the following critical equipment shall undergo a performance check and/or recertification following repair, service or calibration:

- 10.4.1.6 Rapid DNA instrument

- 10.4.2 At a minimum, a Rapid DNA instrument shall undergo a performance check and/or recertification if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory.

11. DOCUMENTATION/REPORTS

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

12. REVIEW

Except as noted below, Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

- 12.2.2 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images). The review of the DNA types may be accomplished by an NDIS-approved and internally validated expert system or internally validated Rapid DNA instrument that uses an NDIS-approved expert system.

- 12.2.3 A review of all controls, Internal Lane Standards and allelic ladders to verify that the expected results were obtained.

- 12.2.5 For modified Rapid DNA analysis, the laboratory shall perform manual technical review of the data generated.

13. PROFICIENCY TESTING

Except as noted below, Standard shall be followed and applied as documented for laboratories that use Rapid DNA analysis or modified Rapid DNA analysis for known reference samples.

- 13.1.1.1 Analysts or technical reviewers performing modified Rapid DNA analysis shall be externally proficiency tested on the interpretation of data generated by a Rapid DNA instrument at least once per year.

14. CORRECTIVE ACTION

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

15. AUDITS

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

16. SAFETY

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

17. OUTSOURCING

Except as noted below, Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

- 17.1.2 A vendor laboratory performing Rapid DNA analysis using a Rapid DNA instrument with an approved STR typing kit and NDIS-approved and internally validated expert system shall verify the correct specimen category for entry into CODIS as part of the technical review under Standard 12.
- 17.7.1 A technical review of DNA data shall include the following elements:
 - 17.7.1.4 For data generated by a vendor laboratory performing Modified Rapid DNA analysis, a review of all notes, all worksheets, and the electronic data (or printed electropherograms or images) supporting the results.
 - 17.7.1.5 For a vendor laboratory using a Rapid DNA instrument, a review of the data associated with applicable Rapid DNA instrument performance checks.